

**ASSEMBLY BILL**

**No. 78**

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**Introduced by Assembly Member Pavley  
(Coauthors: Assembly Members Bass, Chan, Evans, Frommer,  
Gordon, and Koretz)**

January 3, 2005

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An act to add Division 113 (commencing with Section 150000) to the Health and Safety Code, relating to pharmacy benefits management.

LEGISLATIVE COUNSEL'S DIGEST

AB 78, as introduced, Pavley. Pharmacy benefits management.

Existing law provides for the regulation of health care benefits.

This bill would define the term “pharmacy benefits management” as the administration or management of prescription drug benefits. The bill would also define the term “pharmacy benefits manager” as an entity that performs pharmacy benefits management. The bill would require a pharmacy benefits manager to make specified disclosures to its purchasers and prospective purchasers, including specified information about the pharmacy benefit manager’s revenues and its drug formularies, and to make specified disclosures to the public upon request. The bill would also establish certain standards and requirements with regard to pharmacy benefits management contracts and the provision of certain drugs. The bill would impose certain requirements on the membership of a pharmacy and therapeutics committee for a pharmacy benefits manager. The bill would also require a pharmacy benefits manager to meet certain conditions before substituting a prescribed medication.

Vote: majority. Appropriation: no. Fiscal committee: no.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

SECTION 1. Division 113 (commencing with Section 150000) is added to the Health and Safety Code, to read:

DIVISION 113. PHARMACY BENEFITS MANAGEMENT

150000. For purposes of this division, the following definitions shall apply:

(a) "Labeler" means any person who receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the federal Food and Drug Administration under Section 207.20 of Title 21 of the Code of Federal Regulations.

(b) "Pharmacy benefits management" is the administration or management of prescription drug benefits. Pharmacy benefits management shall include all of the following: the procurement of prescription drugs at a negotiated rate for dispensation within this state, the processing of prescription drug claims, and the administration of payments related to prescription drug claims.

(c) "Pharmacy benefits manager" is any person who performs pharmacy benefits management. The term does not include a health care service plan or health insurer if the health care service plan or health insurer offers or provides pharmacy benefits management services and if those services are offered or provided only to enrollees, subscribers, or insureds who are also covered by health benefits offered or provided by that health care service plan or health insurer, nor does the term include an affiliate, subsidiary, or other related entity of the health care service plan or health insurer that would otherwise qualify as a pharmacy benefits manager, as long as the services offered or provided by the related entity are offered or provided only to enrollees, subscribers, or insureds who are also covered by the health benefits offered or provided by that health care service plan or health insurer.

(d) "Prospective purchaser" is any person to whom a pharmacy benefits manager offers to provide pharmacy benefit management services.

1 (e) "Purchaser" is any person who enters into an agreement  
2 with a pharmacy benefits manager for the provision of pharmacy  
3 benefit management services.

4 150001. A pharmacy benefits manager shall disclose to the  
5 purchaser in writing all of the following:

6 (a) The aggregate amount of all rebates and other retrospective  
7 utilization discounts that the pharmacy benefits manager  
8 receives, directly or indirectly, from pharmaceutical  
9 manufacturers or labelers in connection with prescription drug  
10 benefits specific to the purchaser.

11 (b) For a specified list of therapeutic classes, the aggregate  
12 amount for each therapeutic class of all rebates and other  
13 retrospective utilization discounts that the pharmacy benefits  
14 manager receives, directly or indirectly, from pharmaceutical  
15 manufacturers or labelers in connection with prescription drug  
16 benefits specific to the purchaser. A therapeutic class shall  
17 include at least two drugs.

18 (c) The nature, type, and amount of all other revenue that the  
19 pharmacy benefits manager receives, directly or indirectly, from  
20 pharmaceutical manufacturers or labelers in connection with  
21 prescription drug benefits related to the purchaser. A pharmacy  
22 benefits manager shall not be required to disclose the purchase  
23 discounts based upon invoiced purchase terms for prescription  
24 drugs purchased directly or indirectly from a pharmaceutical  
25 manufacturer or labeler for sale and distribution through the mail  
26 order pharmacy of the pharmacy benefits manager.

27 (d) Any prescription drug utilization information related to  
28 utilization by the purchaser's enrollees or aggregate utilization  
29 data that is not specific to an individual consumer, prescriber, or  
30 purchaser.

31 (e) Any administrative or other fees charged by the pharmacy  
32 benefits manager to the purchaser.

33 (f) Any arrangements with prescribing providers, medical  
34 groups, individual practice associations, pharmacists, or other  
35 entities that are associated with activities of the pharmacy  
36 benefits manager to encourage formulary compliance or  
37 otherwise manage prescription drug benefits.

38 (g) Any financial arrangements related to the provision of  
39 pharmacy benefits management to the purchaser that exist

1 between the pharmacy benefits manager and any brokers,  
2 consultants, consulting companies, or other intermediaries.

3 150002. A pharmacy benefits manager shall disclose to a  
4 prospective purchaser in writing all of the following:

5 (a) The aggregate amount of all rebates and other retrospective  
6 utilization discounts that the pharmacy benefits manager  
7 estimates it would receive, directly or indirectly, from  
8 pharmaceutical manufacturers or labelers in connection with  
9 prescription drug benefits related to the prospective purchaser, if  
10 that prospective purchaser were to contract with the pharmacy  
11 benefits manager.

12 (b) For a specified list of therapeutic classes, the aggregate  
13 amount for each therapeutic class of all rebates and other  
14 retrospective utilization discounts that the pharmacy benefits  
15 manager estimates it would receive, directly or indirectly, from  
16 pharmaceutical manufacturers or labelers in connection with  
17 prescription drug benefits specific to the prospective purchaser, if  
18 that prospective purchaser were to contract with the pharmacy  
19 benefits manager. A therapeutic class shall include at least two  
20 drugs.

21 (c) The nature, type, and amount of all other revenue that the  
22 pharmacy benefits manager estimates it would receive, directly  
23 or indirectly, from pharmaceutical manufacturers or labelers in  
24 connection with prescription drug benefits related to the  
25 prospective purchaser, if that prospective purchaser were to  
26 contract with the pharmacy benefits manager. A pharmacy  
27 benefits manager shall not be required to disclose the purchase  
28 discounts based upon invoiced purchase terms for prescription  
29 drugs purchased directly or indirectly from a pharmaceutical  
30 manufacturer or labeler for sale and distribution through the mail  
31 order pharmacy of the pharmacy benefits manager.

32 (d) Any administrative or other fees charged by the pharmacy  
33 benefits manager to the prospective purchaser.

34 (e) Any arrangements with prescribing providers, medical  
35 groups, individual practice associations, pharmacists, or other  
36 entities that are associated with activities of the pharmacy  
37 benefits manager to encourage formulary compliance or  
38 otherwise manage prescription drug benefits.

1 150003. (a) A pharmacy benefits manager shall provide the  
2 information described in Section 150001 no less frequently than  
3 on a quarterly basis.

4 (b) Except for utilization information, a pharmacy benefits  
5 manager need not make the disclosures required in Sections  
6 150001 and 150002 unless and until the purchaser or prospective  
7 purchaser agrees in writing to maintain as confidential any  
8 proprietary information. That agreement may provide for  
9 equitable and legal remedies in the event of a violation of the  
10 agreement. That agreement may also include persons or entities  
11 with whom the purchaser or prospective purchaser contracts to  
12 provide consultation regarding pharmacy services. Proprietary  
13 information includes trade secrets, and information on pricing,  
14 costs, revenues, taxes, market share, negotiating strategies,  
15 customers and personnel held by a pharmacy benefits manager  
16 and used for its business purposes.

17 150004. A pharmacy benefits manager may not execute a  
18 contract for the provision of pharmacy benefits management  
19 services that fails to address the following items:

20 (a) The amount of the total revenues, rebates, and discounts  
21 identified in subdivisions (a), (b), and (c) of Section 150001 and  
22 subdivisions (a), (b), and (c) of Section 150002 that shall be  
23 passed on to the purchaser.

24 (b) The disclosure or sale of enrollee utilization data by the  
25 pharmacy benefits manager to any person or entity other than the  
26 purchaser.

27 (c) Any administrative or other fees charged by the pharmacy  
28 benefits manager to the purchaser.

29 (d) Conditions under which an audit will be conducted of the  
30 contract for pharmacy benefits management services, who will  
31 conduct the audit, and who will pay for the audit.

32 (e) Any revenues, rebates, or discounts received by the  
33 pharmacy benefits manager directly or indirectly from entities  
34 other than manufacturers and labelers that are related to the  
35 services to be provided to the purchaser.

36 (f) The process for development of formularies and  
37 notification of changes to formularies, and approval of those  
38 changes by the purchaser, provided that the pharmacy benefits  
39 manager meets the requirements of Sections 150005, 150006,  
40 and 150007.

1 (g) Whether there is a difference between the price paid to a  
2 retail pharmacy and the amount that will be billed to the  
3 purchaser for prescription drugs.

4 150005. (a) All members of a pharmacy and therapeutics  
5 committee for a pharmacy benefits manager shall be physicians,  
6 pharmacists, academics, or other health care professionals, and a  
7 majority of committee members shall not be employed by the  
8 pharmacy benefits manager.

9 (b) A pharmacy and therapeutics committee member shall not  
10 be an officer, employee, director, or agent of, or any person who  
11 has financial interest in, other than ownership of stock from open  
12 market purchases of less than a nominal amount of the  
13 outstanding stock of, pharmaceutical companies.

14 150006. (a) Except as provided in subdivision (b), any  
15 request from a pharmacy benefits manager to a prescriber for  
16 authorization to substitute a medication shall include all of the  
17 following disclosures:

18 (1) The cost savings for the purchaser, if any, that are a result  
19 of the medication substitution.

20 (2) The difference, if any, in copayments or other  
21 out-of-pocket costs paid by the patient in order to obtain the  
22 medication.

23 (3) The existence of additional payments received by the  
24 pharmacy benefits manager that are not reflected in the cost  
25 savings to the purchaser.

26 (4) The circumstances, if any, under which the currently  
27 prescribed medication will be covered.

28 (5) The circumstances and extent to which, if any, related  
29 health care costs arising from the medication substitution will be  
30 compensated.

31 (6) Any known differences in potential effects on a patient's  
32 health and safety, including side effects.

33 (b) A pharmacy benefits manager shall not be required to  
34 make the disclosures required by subdivision (a) under any of the  
35 following instances:

36 (1) The substitution is from a brand drug to a generic or  
37 chemical equivalent in accordance with applicable state law.

38 (2) The medication substitution is initiated for patient safety  
39 reasons.

1 (3) The currently prescribed medication is no longer available  
2 in the market.

3 (4) The substitution is initiated pursuant to a drug utilization  
4 review.

5 (5) The substitution is required for coverage reasons where the  
6 prescribed drug is not covered by the patient's formulary or plan.

7 (c) A pharmacy benefits manager shall record the name and  
8 title of the prescriber, or the person other than the prescriber,  
9 authorizing the medication substitution if the authorization is  
10 given verbally.

11 (d) The pharmacy benefits manager shall not substitute a  
12 medication for a currently prescribed medication unless the  
13 pharmacy benefits manager communicates with the patient to  
14 provide that patient or their representative the following  
15 information:

16 (1) The proposed medication and the currently prescribed  
17 medication.

18 (2) The difference in copayments or other out-of-pocket costs  
19 paid by the patient, if any.

20 (3) Potential side effects of the medication substitution.

21 (4) The circumstances, if any, under which the currently  
22 prescribed medication will be covered.

23 (5) The circumstances and the extent to which, if any, health  
24 care costs related to the medication substitution will be  
25 compensated.

26 (6) Notification that the patient may decline the medication  
27 substitution if the currently prescribed drug remains on the  
28 patient's formulary, and the patient is willing to pay any  
29 difference in the copayment amount.

30 (7) A toll-free telephone number to communicate with the  
31 pharmacy benefits manager.

32 (e) The pharmacy benefits manager shall cancel and reverse  
33 the medication substitution upon written or verbal instructions  
34 from a prescriber or the patient. The pharmacy benefits manager  
35 shall not be required to cancel and reverse the medication  
36 substitution if the prescribed drug is no longer on the purchaser's  
37 formulary or the patient is unwilling to pay a higher copayment  
38 or other cost associated with the prescribed drug.

39 (f) The pharmacy benefits manager shall maintain a toll-free  
40 telephone number during normal business hours for a minimum

1 of eight hours per day Monday through Friday for prescribers  
2 and patients.

3 (g) The pharmacy benefits manager shall not charge the  
4 individual any additional copayments or fees related to the  
5 replacement medication.

6 150007. A pharmacy benefits manager shall monitor the  
7 health effects on patients of medication substitutions requested  
8 by the pharmacy benefits manager. The pharmacy benefits  
9 manager shall, on a quarterly basis, report to his or her Pharmacy  
10 and Therapeutics Committee the results of the monitoring. This  
11 report shall include all patient and prescriber communications  
12 received by the pharmacy benefits manager that concern the  
13 efficacy or health effects of the medication substitutions.

14 150008. All disclosures made pursuant to this division shall  
15 comply with the privacy standards of the federal Health  
16 Insurance Portability and Accountability Act.

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19 **CORRECTIONS:**

20 **Heading — Lines 1 and 2.**

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